

PATENT
Application No.: 10/627,591
Attorney Docket No. 0029.10

REMARKS

Claims 23-52 are presently pending in the case. Reconsideration of the present case is requested.

Claim rejections under 35 USC 102

The Examiner rejected claims 23, 24, 33, 35, 38, 39, 42-44, 47, 48 and 50 under 35 USC 102(b) as being anticipated by U.S. Patent 4,036,919 to Komendowski et al (hereinafter Komendowski et al). The rejection is traversed.

Komendowski et al does not anticipate independent claim 23. To sustain a section 102 rejection, the reference relied upon, must disclose each and every element of the claimed invention. Non-disclosure of a single element of the claim negates anticipation. Claim 23 is to a device comprising, inter alia, a flow restrictor for limiting the flow of an aerosolized active agent formulation to a human patient to less than 17 liters per minute. Komendowski et al has no such flow restrictor. The Examiner points to element 27 of Komendowski et al, but element 27 refers to perforations for gas diffusion and nebulization and are not related to the flow rate to the human patient. It is respectfully submitted that this positively recited feature is absent in the disclosure of Komendowski et al, thereby precluding a section 102 rejection because each and every element of the claim is not within the cited reference. Thus, the Examiner is respectfully requested to reconsider the language of claim 23 and withdraw the rejection thereunder.

Independent claim 33 is also not anticipated by Komendowski et al. Claim 33 is to a device adapted to deliver an aerosolized active agent formulation at an inspiratory flow rate of less than 17 liters per minute. Since Komendowski et al does not disclose this limitation, as discussed above, it does not anticipate claim 33.

Komendowski et al also does not anticipate independent claim 38. Claim 38 recites "a flow restrictor to restrict an inspiratory flow rate of an aerosolized ... formulation to less than 17 liters per minute." Since Komendowski et al does not disclose this limitation, as discussed above, it does not anticipate claim 38.

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Komendowski et al also does not anticipate independent claim 42. Claim 42 recites "one or more orifices sized so that an aerosolized active agent formulation may be delivered at an inspiratory flow rate of less than 17 liters per minute." Since Komendowski et al does not disclose this limitation, as discussed above, it does not anticipate claim 42.

Komendowski et al also does not anticipate independent claim 47. Claim 47 recites "means for limiting an inspiratory flow rate through the mouthpiece to less than 17 liters per minute." Since Komendowski et al does not disclose this limitation, as discussed above, it does not anticipate claim 42.

Claims 24-32, 34-37, 39-41, 43-46 and 48-52 depend from one of claims 23, 33, 38, 42 and 47 and are not anticipate by Komendowski et al for at least the same reason as the claims from which they depend.

Claim rejections under 35 USC 103(a)

The Examiner rejected claims 25, 27-29, 30-32, 34, 36, 37, 40, 41, 45, 46, 51, and 52 under 35 USC 103(a) as being unpatentable over Komendowski et al. The rejection is traversed.

Claims 25, 27-29, 30-32, 34, 36, 37, 40, 41, 45, 46, 51 and 52 are not rendered unpatentable by Komendowski et al. Each of claims 25, 27-29, 30-32, 34, 36, 37, 40, 41, 45, 46, 51 and 52 recite a flow restrictor limitation, as discussed above. For each of the respective limitations, Komendowski et al fails to disclose the recited restrictor. Komendowski et al also does not teach the necessary features and one of ordinary skill in the art would not have been motivated to modify Komendowski et al in a manner that would arrive at Applicant's invention. Accordingly, claims 25, 27-29, 30-32, 34, 36, 37, 40, 41, 45, 46, 51 and 52 are not rendered unpatentable by Komendowski et al.

The Examiner rejected claims 23 and 26 under 35 USC 103(a) as being unpatentable over U.S. Patent 5,740,794 to Smith et al (hereinafter Smith et al) in view of Komendowski et al (note: Applicant presumes Examiner intended to include Komendowski et al in this rejection).

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Smith et al and Komendowski et al do not render claims 23 and 26 unpatentable. Claim 23 is to a device comprising a flow restrictor for limiting the flow of an aerosolized active agent formulation to a human patient to less than 17 liters per minute. Smith et al does not disclose the recited flow restriction and Komendowski et al fails to teach the recited flow restriction, as discussed above. Accordingly, claim 23 and claim 26 which depends therefrom are not rendered unpatentable by Smith et al and Komendowski et al.

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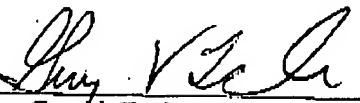
Conclusion

Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

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